Long Term Care Antigen Testing Guidance
12.28.2020

Background

On Tuesday, July 14, 2020, the U.S. Department of Health and Human Services (HHS) announced it would be providing rapid point of care testing devices and tests to long term care facilities in COVID-19 hotspots in the U.S. HHS will determine the facilities that will be receiving the testing equipment. It is the Department's understanding at this time that facilities will be receiving either Quidel Sofia 2 Instrument or the BD Veritor Plus system – along with 400 of the associated tests. The Iowa Department of Public Health (IDPH) and State Hygienic Laboratory (SHL) will not be involved in determining which testing equipment each facility receives. Those determinations will also be made by HHS. Following the initial distribution of the testing equipment and test supplies, facilities will be responsible for ordering their own additional testing supplies.

Receipt of the rapid point of care testing devices is contingent upon a facility's possession of a CLIA waiver. Questions about how to obtain a CLIA waiver should be directed to the State Hygienic Lab at (319) 335-4500. Additional information about obtaining CLIA certificates of waiver can also be found on the CMS website.

This document serves to provide guidance on how to use these testing devices in a long term care setting. The guidance may be updated as new information becomes available. Additionally, facilities that receive these testing devices will also be offered training materials from SHL.

Guidance for Use

1. Rapid Testing for Symptomatic Residents and Staff

   It is anticipated this equipment will be useful for identifying positive cases quickly in congregate settings, such as long term care facilities. In accordance with manufacturer instructions, this testing equipment can be used for the rapid testing of symptomatic staff or residents.

   If a positive result is received using the rapid testing equipment, the appropriate isolation protocols for residents and staff must immediately be followed and the results should be reported to public health.

   It is important to know that there is the possibility of a false negative test. If a negative test result is received for a resident or staff member for whom COVID-19 infection is highly suspected, IDPH and SHL recommend conducting a confirmatory diagnostic PCR test. The package insert states: "Negative results should be treated as presumptive and confirmed with an FDA authorized molecular assay, if necessary, for clinical management, including infection control." Confirmatory diagnostic PCR testing supplies can be obtained through the SHL or other reference laboratory used by the long term care facility. Instructions for ordering testing supplies from the SHL can be found in Appendix A of the Long-Term Care Facilities Visitation Guidance.

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Specifications for Use

1. CLIA Certificate of Waiver

   To perform this testing the facility must have a current CLIA certificate of waiver. To obtain a certificate of waiver, the facility is required to comply with all CLIA documentation and other requirements. Questions about obtaining a CLIA certificate of waiver should be directed to SHL at (319) 335-4500.

   This testing is deemed a waived test for CLIA which means facilities are required to follow manufacturer's instructions when using these test systems.

   Positive and negative external quality control is required with each new lot/shipment of cartridges. If you receive a new shipment or new lot number you must perform the external quality control.

2. Effect of Acceptance.

   By accepting this instrument and its associated test cartridges and controls you are agreeing and authorized to use the equipment for testing only for your long term care facility, you are not authorized to perform testing for other facilities.

3. Training.

   Training to perform this testing using this equipment is an important component of adhering to the CLIA requirements. All staff performing testing are required to read the package insert and document that they have done so. The procedure detailed in the package insert must be followed exactly and safety guidance should be followed.

4. Results Reporting.

   Reporting to IDPH of both positive and negative test results is required. Facilities that receive these machines will be contacted by IDPH to establish a mechanism to electronically report all tests performed (**both positive and negative results**) to IDPH the same day the testing was performed. Facilities with questions related to reporting should contact John Satre at IDPH by calling (515) 229-0417.

5. Biosafety Risk Assessments.

   A biosafety risk assessment must be performed before testing is performed. Use appropriate PPE to perform the test. **Clean and disinfect the area around the instrument after each test performance.**

FAQs

Clinical:

1. CMS has told us that the two testing systems they plan to distribute to all facilities, Quidel Sofia 2 SARS Antigen FIA and BD Veritor System for Rapid Detection of SARS-CoV-2, and now the Abbot BinaxNOW are intended to be used for surveillance testing in nursing facilities for residents, staff, and visitors. What would IDPH's concerns be with these two particular antigen testing POC systems, if any?

   A: Recommendations for use of the POC equipment is found above.

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2. Can you confirm that facilities with a CLIA Waiver will be able to process these tests without further requirements?

   A: Yes, this is correct. Facilities with a CLIA certificate of waiver will be able to receive and use the POC testing equipment sent.

3. How will IDPH view POC testing accuracy? Will positive tests require subsequent PCR confirmation testing? What about symptomatic residents who test negative? Could a facility rerun the test, or would a PCR confirmation be required?

   A: As indicated in the above guidance, Iowa Department of Public Health recommends that positive tests from the POC testing equipment be treated as an infection. If an individual is symptomatic and suspected to have COVID but receives a negative test result from the POC equipment provided, it is recommended that the individual is retested by PCR to ensure that it is not the result of a false negative

Operations:

4. Who will be allowed to collect the specimens? Who will be allowed to run the lab testing equipment?

   A: Any medical professional that has received training and is documented as competent will be considered allowed to collect specimens. Individuals must have documented training to run the lab testing equipment but do not require specific medical license or education.

5. What types of control testing and logs will be required?

   A: Materials related to quality control testing and necessary logs will be provided to the facility based on the type of POC equipment that was received.

Reimbursement:

6. It appears that Medicare will pay for this testing for residents. If a resident does not have Medicare coverage, may the facility bill Medicaid for testing and how will that be billed?

   A: Yes, the facility may bill Medicaid but should confirm that they are appropriately enrolled with the Iowa Medicaid Enterprise and applicable managed care organizations to bill for lab services.

7. Will the state cover the costs of staff testing with these POC systems? If so, how would we bill this?

   A: The state is working with federal partners to understand the intended use of federal COVID provider relief funds. More information will be provided when available.

8. How will facilities be able to cover the cost of visitor testing?

   A: The Iowa Department of Human Services does not recommend that the POC testing equipment provided to facilities be used for screening visitors at this time. Standard protocols for screening should continue to be followed.

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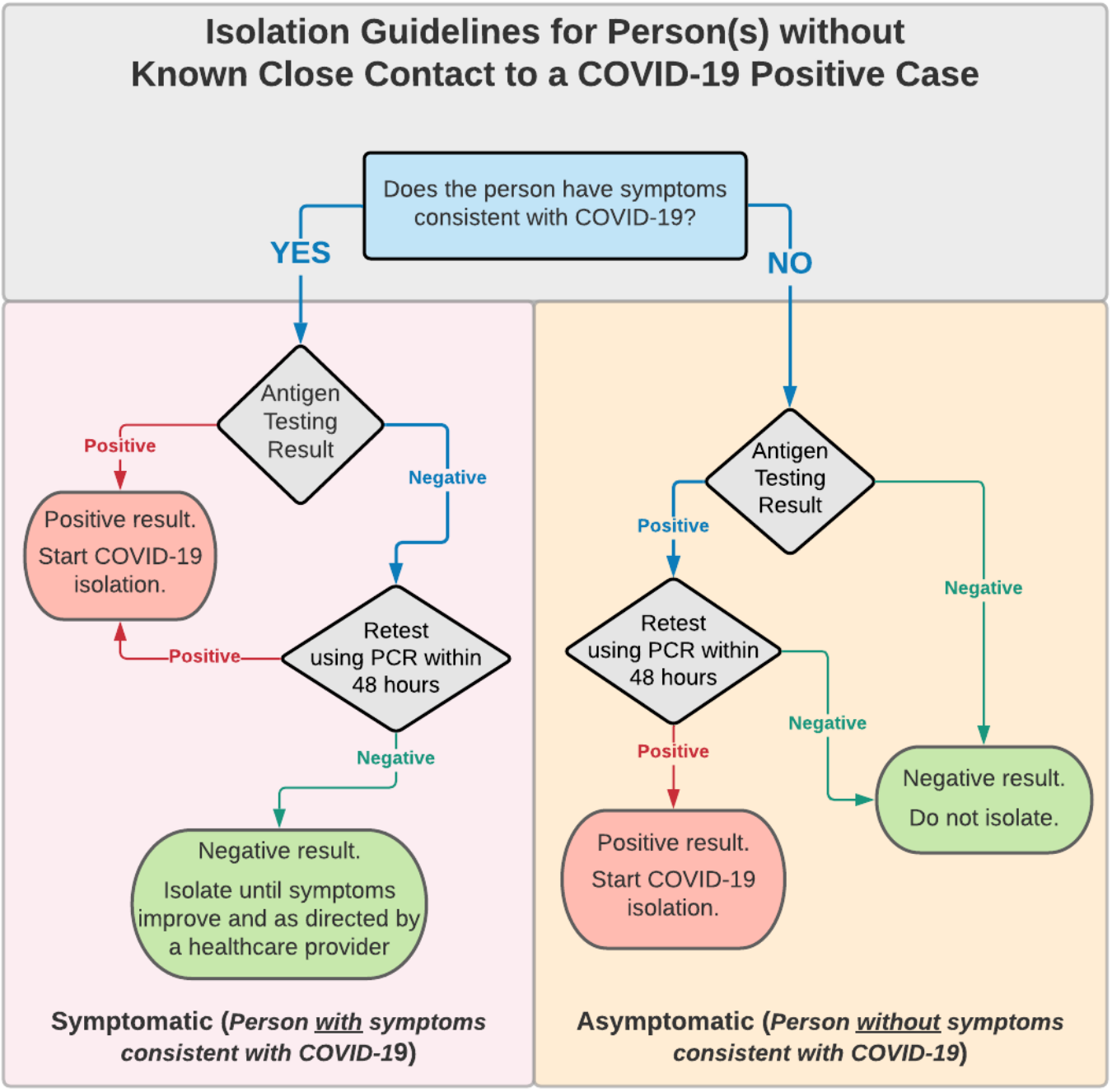

This guidance is subject to change as federal guidance is released and clarified, and as additional Iowa-specific data is collected.

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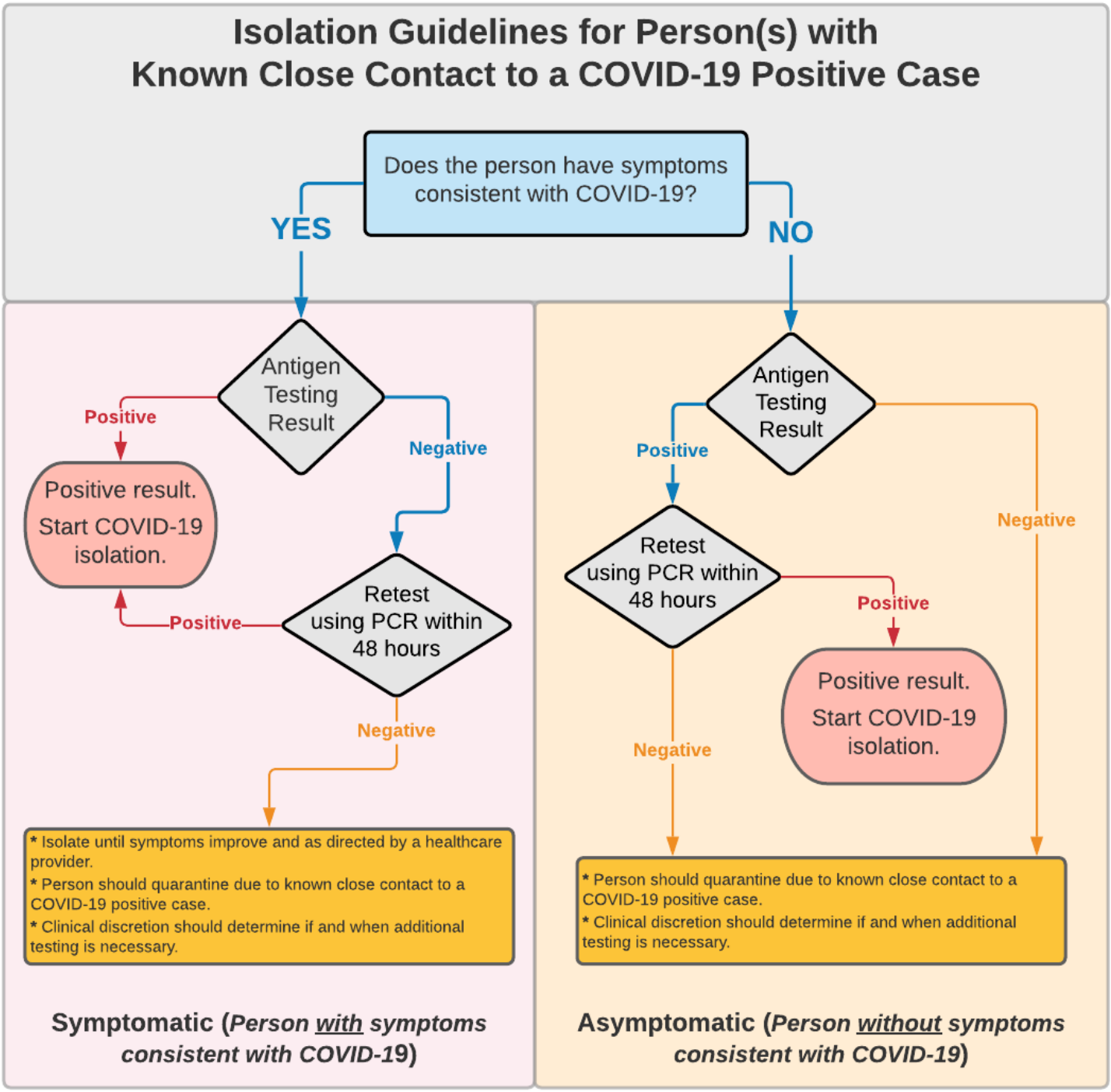
Isolation Guidelines for Person(s) with Known Close Contact to a COVID-19 Positive Case



Symptomatic (*Person <u>with</u> symptoms consistent with COVID-19*)

Asymptomatic (*Person <u>without</u> symptoms consistent with COVID-19*)

LTC Staff Guidance:

All ASYMPTOMATIC staff testing POSITVE on antigen testing **SHOULD** be re-tested using confirmatory PCR testing. The PCR specimen must be collected within 48 hours of when the positive antigen specimen was collected.

ASYMPTOMATIC staff members WITHOUT known close contact with a COVID-19 positive case:
When PCR results are pending, the ASYMPTOMATIC staff member WITHOUT known close contact with a COVID-19 infected case should start COVID-19 isolation and public health will advise close contacts to start a COVID-19 quarantine.

- If the PCR result is NEGATIVE, the ASYMPTOMATIC staff member should stop COVID-19 isolation and return to work. Close contacts should stop their COVID-19 quarantine.
- If the PCR is POSITIVE, the ASYMPTOMATIC staff member should complete COVID-19 isolation. Close contacts should complete their COVID-19 quarantine.

ASYMPTOMATIC staff members WITH known close contact with a COVID-19 positive case:
When PCR results are pending, the ASYMPTOMATIC staff member WITH known close contact with a COVID-19 infected case should start COVID-19 isolation and public health will advise close contacts to start a COVID-19 quarantine.

- If the PCR result is NEGATIVE, the ASYMPTOMATIC staff member should stop COVID-19 isolation and complete their COVID-19 quarantine (*due to known close contact with a COVID-19 positive case*). Close contacts should stop their COVID-19 quarantine.
- If the PCR is POSITIVE, the ASYMPTOMATIC staff member should complete COVID-19 isolation. Close contacts should complete their COVID-19 quarantine.

All SYMPTOMATIC staff members testing NEGATIVE with point of care antigen testing **SHOULD** be re-tested using confirmatory PCR testing. The PCR specimen must be collected within 48 hours of when the positive antigen specimen was collected.

SYMPTOMATIC staff members WITHOUT known close contact with a COVID-19 positive case:
When PCR results are pending, the SYMPTOMATIC staff member should isolate themselves and be excluded from working. Public health will not perform an investigation or contact trace unless the PCR results are positive.

- If the PCR is NEGATIVE, the SYMPTOMATIC staff member can return to work after their symptoms resolve in accordance with the facility's established procedures.
- If the PCR is POSITIVE, the SYMPTOMATIC staff member should complete COVID-19 isolation and public health will perform an investigation and contact trace.

SYMPTOMATIC staff members WITH known close contact with a COVID-19 positive case:
When PCR results are pending, the SYMPTOMATIC staff member should isolate themselves and be excluded from working. Public health will not perform an investigation or contact trace unless the PCR results are positive.

- If the PCR is NEGATIVE, the SYMPTOMATIC staff member should stop COVID-19 isolation and complete their COVID-19 quarantine (*due to known close contact with a COVID-19 positive case*).
- If the PCR is POSITIVE, the SYMPTOMATIC staff member should complete COVID-19 isolation and public health will perform an investigation and contact trace.

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LTC Resident Guidance:

All ASYMPTOMATIC residents testing POSITVE on antigen testing **SHOULD** be re-tested using confirmatory PCR testing. The PCR specimen must be collected within 48 hours of when the positive antigen specimen was collected.

ASYMPTOMATIC resident WITHOUT known close contact with a COVID-19 positive case:
When PCR results are pending in ASYMPTOMATIC residents WITHOUT known close contact with a COVID-19 infected case should be transferred to a single room if there is a roommate, implement use of Transmission-Based Precautions, and dedicate staff. The LTC facility should not transfer the ASYMPTOMATIC resident to the COVID-19 Unit or place them in another shared room with new roommates. Public health will advise close contacts to start a COVID-19 quarantine.

- If the PCR result is NEGATIVE, the ASYMPTOMATIC resident can be transferred back to their original room, Transmission-Based Precautions can be discontinued and dedicated staff can be stopped. Close contacts should stop their COVID-19 quarantine.
- If the PCR is POSITIVE, the ASYMPTOMATIC resident should be transferred to the COVID-19 Unit to complete their COVID-19 isolation. Close contacts should complete their COVID-19 quarantine.

ASYMPTOMATIC residents WITH known close contact with a COVID-19 positive case:
When PCR results are pending, the ASYMPTOMATIC residents WITH known close contact with a COVID-19 infected case should be transferred to a single room if there is a roommate, implement use of Transmission-Based Precautions, and dedicate staff. The LTC facility should not transfer the ASYMPTOMATIC resident to the COVID-19 Unit or place them in another shared room with new roommates. Public health will advise close contacts to start a COVID-19 quarantine.

- If the PCR result is NEGATIVE, the ASYMPTOMATIC resident should continue to be cared for using the pending test guidance and complete their COVID-19 quarantine (*due to known close contact with a COVID-19 infected case*). Close contacts should stop their COVID-19 quarantine.
- If the PCR is POSITIVE, the ASYMPTOMATIC resident should be transferred to the COVID-19 Unit to complete their COVID-19 isolation. Close contacts should complete their COVID-19 quarantine.

All SYMPTOMATIC residents testing NEGATIVE with point of care antigen testing **SHOULD** be re-tested using confirmatory PCR testing. The PCR specimen must be collected within 48 hours of when the positive antigen specimen was collected.

SYMPTOMATIC residents WITHOUT known close contact with a COVID-19 infected case:
When PCR results are pending in SYMPTOMATIC residents WITHOUT known close contact with a COVID-19 infected case should be transferred to a single room if there is a roommate, implement use of Transmission-Based Precautions, and dedicate staff. The LTC facility should not transfer the SYMPTOMATIC resident to the COVID-19 Unit or place them in another shared room with new roommates. Public health will not perform an investigation or contact trace unless the PCR results are positive.

- If the PCR is NEGATIVE, when the SYMPTOMATIC resident's symptoms resolve, the resident can be transferred back to their original room, Transmission-Based Precautions can be discontinued and dedicated staff can be stopped in accordance with facility procedures.
- If the PCR is POSITIVE, the SYMPTOMATIC resident should be transferred to the COVID-19 Unit to complete their COVID-19 isolation. Public health will perform an investigation and contact trace.

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SYMPTOMATIC residents WITH known close contact with a COVID-19 infected case:

When PCR results are pending in SYMPTOMATIC residents WITH known close contact with a COVID-19 positive case should be transferred to a single room if there is a roommate, implement use of Transmission-Based Precautions, and dedicate staff. The LTC facility should not transfer the SYMPTOMATIC resident to the COVID-19 Unit or place them in another shared room with new roommates. Public health will not perform an investigation or contact trace unless the PCR results are positive.

- If the PCR is NEGATIVE, the SYMPTOMATIC resident should continue to be cared for using the pending test guidance and complete their COVID-19 quarantine (*due to known close contact with a COVID-19 infected case*). Close contacts should stop their COVID-19 quarantine.
- If the PCR is POSITIVE, the SYMPTOMATIC staff member should be transferred to the COVID-19 Unit to complete their COVID-19 isolation. Public health will perform an investigation and contact trace.

NOTE: Any person(s) with signs and symptoms consist with COVID-19, regardless if they are a staff member or resident of a long-term care facility, **AND** a positive antigen test should start a COVID-19 isolation. Symptomatic person(s) with a positive antigen test do not need further testing by PCR.

Reporting False Positives and False Negatives:

LTC facilities should consider reporting false positive and false negative antigen results through FDA's medwatch (in addition to public health): www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-eventreporting-program

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Antigen Testing Technical Pointers:

- Thoroughly read the package insert before performing the test and follow all instructions.
- Store reagents at the recommended temperatures and bring refrigerated reagents to room temperature before use.
- Change gloves between each patient specimen to avoid cross contamination
- **DO NOT** use viral transport media.
- Test samples within the specified time after collection. *For example, BinaxNOW cards must be tested within 1 hour of collection.*
- **DO NOT** use expired reagents or damaged test cassettes/devices.
- Document proper timing for reading the results when testing multiple specimens at the same time.
- Use the test cassette/device within specified time after opening.
- **ALWAYS** keep the test device in a horizontal position when in use.
- Results must be interpreted within specified times frames. *For example, BinaxNOW cards must be read promptly at 15 minutes after the swab is inserted. Do not read results before 15 minutes or after 30 minutes and record the time the results were read.*
- Read results exactly as described in the package insert.
- When complete and between samples, disinfect work surfaces and equipment with an EPA-approved disinfectant for SARS-CoV-2.

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- To document competency have staff view the relevant video:
  - BinaxNOW: https://www.youtube.com/watch?v=nYTePdZBbLU
  - BD Veritor: https://www.youtube.com/watch?v=wJJRPS7pu44
  - Quidel Sofia: https://www.youtube.com/watch?v=D7xJ2LQ4IV4

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Missing Swabs from Antigen Kits:

For all emergency use authorization (EUA) cleared test systems the laboratory must follow the instructions for use (IFU). Laboratories must follow collection procedures as written. For example:

- If the IFU states a nasopharyngeal (NP) swab must be used to perform the test, the lab cannot collect a nasal swab to perform the test if NP swabs are not available.
- If the IFU states to use NP swab, but does not list a specific brand, then the laboratory is free to use any NP swab available.

A more specific example is the Abbott ID Now, the IFU states, "*For optimal test performance, use the swabs provided in the test kit. Alternatively, foam, polyester, HydraFlock® and nylon flocked throat swabs can be used to collect throat swab samples. Rayon swabs are not suitable for use in this assay.*" In this case, the laboratory could not use Rayon swabs, but any of the others listed would be acceptable. The IFUs are different for each test system, so be sure to review the entire IFU. – submitted by Kristi Rotzoll, CLIA Compliance Specialist

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